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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/785,532	01/17/1997	JOE W. GRAY	2500.124US2	4124

22798 7590 03/22/2006

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EXAMINER

DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

08/785,532

Applicant(s)

GRAY ET AL.

Examiner

MINH-TAM DAVIS

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1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 26-28,37 and 61-63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-28,37 and 61-63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. <u>02/22/06</u> |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                                  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____   |

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly, claims 26-28, 37, 61-63, SEQ ID NO:9 are examined in the instant application.

The following are the remaining rejections.

### **OBJECTION**

The specification is objected to because it contains empty space, for example on page 2, line 17.

### **REJECTION UNDER 35 USC 102 (b), NEW REJECTION**

Claims 26-28, 37, 61-63 are rejected under 35 U.S.C. 102(b) as being anticipated by Tanner, MM et al, 1994, Cancer Research, 54: 4257-42660, of record.

Claims 26-28, 37, 61-63 are drawn to:

A method for detecting breast cancer, comprising contacting a nucleic acid sample from breast tissue cells of a human patient with a probe, that specifically hybridizes under stringent conditions as recited in claim 26, and detecting an increased in copy number of nucleic acid sequences at chromosome region 20q13.2 (claims 26-27).

The nucleic acid sample is a metaphase spread or an interphase nucleus (claim 28), or is a chromosome (claim 63).

The probe comprises SEQ ID NO:9, wherein the probe is labeled or is labeled with fluorescent label (claims 37, 61-62).

Tanner et al teach detection of an increased gene copy number at 20q13 in primary breast cancer, using as a probe the cosmid RMC20C001, with an Flpter value of 0.825 (p.4259, item under Results) and interphase fluorescence in situ hybridization (abstract and p.4257, second column, under Preparation of cell lines and primary breast tumors for FISH, p.4259, first column, first two paragraphs).

The specification discloses that the probe RMC20C001 is known in the art (Flpter 0.824; 20q13.2), and refers to Tanner, MM et al, 1994, Cancer Research, 54: 4257-42660 (p.13, lines 14-15, p.14, lines 7-9, p.47, lines 19-22). The specification also discloses that the probe RMC20C001 is used in the instant application (p.47, lines 19-22), wherein said probe detects amplification of a region of the chromosome 20q13.2 in primary breast carcinomas (p.49), and that SEQ ID NO:9 lies within the amplified 20q13 region complementary to RMC20C001 (figure 5).

The probe taught by Tanner et al seems to be the same as the claimed probe.

Although the reference does not specifically teach that the probe hybridizes to SEQ ID NO:9 under the stringent conditions cited in claim 1, however, the claimed probe appears to be the same as the prior art probe. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those

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taught by the prior art and to establish patentable differences. See *In re Best* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Further, the method taught by Tanner et al seems to be the same as the claimed method.

Because the method of the prior art comprises the same method steps as claimed in the instant invention using the same composition, the claimed method is anticipated because the method will inherently lead to the claimed effects. See *Ex parte Novitski* 26 USPQ 1389 (BPAI 1993).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

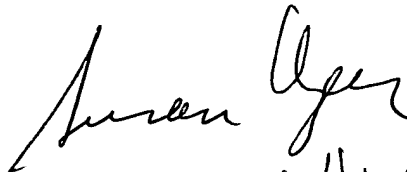
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MINH TAM DAVIS

March 07, 2006

  
Susan Ungor  
Primary Patent Examiner